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IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, dba LABCORP.,

Petitioner,

v.

METABOLITE LABORATORIES, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* BOSTON PATENT LAW ASSOCIATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

The Boston Patent Law Association ("BPLA") is a non-profit association of intellectual property professionals providing programs and forums for the exchange of ideas and information about patent and other intellectual property rights. The BPLA files this *amicus* brief in support of Respondents, but remains neutral as to the outcome of the case. The BPLA is concerned how the analysis of patent eligible subject matter will impact inventors and their ability to protect their intellectual property rights.

INTRODUCTION

The question presented for review by the Court is whether the method encompassed by Claim 13 of U.S. Patent 4,940,658 (hereinafter the '658 patent) is indefinite, undescribed, and non-enabling.[2] As presented, the question

1. The parties have consented to the filing of this brief *amicus curiae*. The letters of consent have been filed with the Clerk of the Court. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae* or its counsel.

2. The question presented is

> Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

begs the real issue of subject matter eligibility that is the focus of much of Petitioner's argument, and argument presented by numerous amici and commentators. Thus, the essential question presented for review is whether Claim 13, as issued, covers patentable subject matter under 35 U.S.C. § 101.[3]

It is fitting that the analysis of the patentability of Claim 13, and the resulting impact on scientific and technological progress resulting from the confirmation of its patentability, begin with the issue of statutory subject matter. Although the issue of patentability of Claim 13 during prosecution of the application before the Patent Office and subsequent review of patentability by the District Court for the District of Colorado and Court of Appeals for the Federal Circuit did not address this essential question, statutory subject matter is certainly the threshold question to be asked. For if the subject mater covered by the claim does not fall within statutory decree, then no need exists for further inquiry into the issues of definiteness, written description and enablement (as well as novelty and non-obviousness). The initial hurdle of compliance with statutory subject matter must be overcome before these subsequent limits on patentability are determined.

The analysis of patent eligible subject matter becomes much more difficult when one must further determine whether the subject matter falls within one of the judicially created exceptions to patentablity: laws of nature, natural phenomena, or abstract ideas.

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3. 35 U.S.C. § 101 reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

But even after determination that the claimed subject matter is not excluded from patentability, the inquiry must go even further to address the policy concerns underlying patent eligibility. Would confirmation of the patentability of the subject matter covered by the claim at issue remove crucial knowledge from the public domain?

Our position is that the process covered by Claim 13 does encompass patentable subject matter under 35 U.S.C. § 101, and that confirming the patentability of Claim 13 will not preempt scientific knowledge from the public domain.[4]

ARGUMENT

I. When Read as a Whole, Claim 13 Encompasses Patentable Subject Matter Under 35 U.S.C. § 101

A. The Constitution and Congress Promote a Wide Range of Patent Eligible Subject Matter

Art. 1, § 8, clause 8 of the U.S. Constitution recites a sweeping directive to promote progress of useful arts by conferring exclusivity to an invention for a limited time to the inventor(s). The first U.S. Patent Acts of 1790 and 1793 defined the statutory categories of patentable subject matter as a useful art, machine, manufacture, composition of matter or any improvement therein. These categories were confirmed

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4. It is also paramount to remember that, although the analysis herein focuses on the determination of § 101 patent eligible subject matter, additional statutory and judicial constraints on patentability must also be considered. For example, the statutory requirements of 35 U.S.C. § 112 (definiteness, written description, and enablement), § 102 (novelty), and § 103 (non-obviousness) must still be met before a claim can be deemed patentable.

by the U.S. Patent Act of 1952 with a bit of modernization by changing the term "art" to "process."

The intent of the Constitution and Congress is clear. In return for an inventor's full disclosure of the invention to the public, the inventor can enjoy the recognition and economic benefits of the invention for a limited time. The "quid pro quo" is a limited time of monopoly for the dissemination of details of the invention so that one of skill in the art can understand and practice the invention. Without the grant of exclusivity for the invention, inventors would keep their technological innovations from the public, thus precluding others from learning of and improving on the technology.

Technological innovation has advanced significantly since the passing of the last Patent Act in 1952. With huge advances in science and technology leading to inventions that were only "science fiction" in 1952, Congress and the courts have had to define, refine, and impose limits on the scope of statutory subject matter while still adhering to the mission of promoting the progress of the arts and sciences. Although the courts agree that "Congress intended statutory subject matter to 'include anything under the sun that is made by man,'" *Diamond v. Diehr*, 450 U.S. 175, 182 (1981), limits have been set, and fine lines have been drawn to exclude from patent protection "laws of nature, physical phenomena and abstract ideas." *Id.* at 185. How to determine whether claimed subject matter is patent eligible or excluded has been the subject of numerous decisions. *See, e.g., Diamond v. Diehr*, 450 U.S. 175 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Funk Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). These decisions have led to three categories of subject matter excluded from the scope of patent eligible

subject matter. Laws of nature (*e.g.*, $E=mc^2$), physical phenomena, and abstract ideas, such as mathematical algorithms, are not patentable. Laws of nature or scientific principles are fundamental truths outside the scope of the statute.[5]

But what if the scientific principle is not an "always-existing" fundamental truth? What if there are variations of the "truth" under certain conditions? What if it could be $E=m^2c$ under certain conditions and $E=mc^2$ under other conditions? That is, when is a "fundamental truth" not "fundamental" and thus patent eligible subject matter? It would be reasonable to propose that, when analysis is required to determine under which conditions the scientific principle applies, or when correlation of a particular condition to the scientific principle is required, the fundamental truth is no longer fundamental and is eligible for patent protection.

B. The Presence of a Law of Nature, Natural Phenomena or Abstract Idea in a Claim Does Not Automatically Exclude the Claim from the Realm of Statutory Subject Matter

The "application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection," *Diehr*, 450 U.S at 187; *see also Parker v. Flook*, 437 U.S. 584, 590 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). If the claimed process results in a physical transformation for which a practical application is disclosed in the specification or

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5. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right". *LeRoy v. Tatum*, 55 U.S. (14 How.) 156, 175 (1982); *See also Funk Brothers Seed Co.*, 333 U.S. 127, 132 (1948); *Chakrabarty*, 447 U.S. at 309.

known to one of skill in the art, or if the claimed process is limited to a practical application which produces a useful, tangible and concrete result, the claimed process encompasses statutory subject matter. *See Diehr*, 450 U.S. at 183-84 quoting *Cochrane v. Deneer*, 94 U.S. 780, 787-88 (1877). The claimed invention as a whole must accomplish a practical application and a useful, concrete, and tangible result. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d. 1368, 1374 (Fed. Cir. 1998); Manual of Patent Examining Procedure (MPEP) 2106 (II)(A) August 2005. Patentable inventions should have practical value as opposed to "subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research." MPEP 2106 (II)(A) August 2005. *See also Brenner v. Manson*, 383 U.S. 519 (1966); *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1059 (Fed. Cir. 1992); *AT&T Corp. v. Excel Communications, Inc.*, 173 F.3d 1352, 1358 (Fed. Cir. 1999); *In re Alappat*, 33 F.3d 1526, 1543 (Fed. Cir. 1994).

Admittedly, it is a difficult analysis. When does the application of a law of nature or a scientific principle satisfy the requirements of patent eligible subject matter? When does a claim containing a scientific principle transcend the line between an unpatentable claim covering the principle itself to a patentable claim that uses that principle in a process which, "when considered as a whole is performing a function which the patent laws were designed to protect?" *Diehr*, 450 U.S. at 192. The focus must be on whether there is a transformation from mere statement of principle to useful result.

It is also well-established law that assessment of patentability of a claim must evaluate the claim as a whole.

> In determining the eligibility of respondents' claimed process for patent protection under 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.

Diehr, 450 U.S. at 188-89.

Moreover, not only the active steps of the process can be considered in the analysis. If the preamble "breathes life and meaning into the claim" and limits the claimed invention, then the preamble must be treated as a claim limitation.[6] In determining whether an inventor seeks patent protection for a bare scientific principle, or a useful application of that principle, the claim as a whole, at times including the limitations of the preamble, must be considered.

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6. The preamble of a claim directed to a method of treating or preventing anemia by administering certain vitamin preparations to a human "in need thereof" was not "merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed." MPEP 2111.02(II) quoting *Jansen v. Rexall Sundown, Inc.*, 342 F.3d. 1329, 1333-34 (Fed. Cir. 2003).

C. When Read as a Whole, Claim 13 Encompasses Patentable Subject Matter

Claim 13 reads:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> Assaying a body fluid for an elevated level of total homocysteine; and
>
> Correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

During prosecution of the application before the United States Patent Office, the Patent Examiner required the "correlating" phrase to be included in the claim so that the step of assaying a body fluid is clearly related to the preamble. The preamble of Claim 13 is to be given "meaning," whereby the claimed steps of assaying and correlating are performed to detect, if present, a deficiency of cobalamin or folate in a subject. Clearly the Patent Office believed that the purpose of the process, to detect a deficiency of cobalamin or folate, gave meaning to the claim and should not be discounted in the analysis of patentable subject matter. Thus, when read "as a whole," the claimed invention encompasses (as paraphrased into a more conversational recitation):

> A process for detecting a B vitamin deficiency in a subject by analyzing a body fluid obtained from the subject by performing a homocysteine assay to determine the amount of homocysteine in the

body fluid and relating the levels of homocysteine in the body fluid to a determination of whether or not there is a B vitamin deficiency.

When read as a whole, does this claim cover a scientific principle? Is it a fundamental truth that every time there is an elevated homocysteine level in a blood sample the subject suffers from a B vitamin deficiency? An elevated level of total homocysteine can result from other causes and is not necessarily the consequence of a vitamin deficiency. For example, a genetic defect exists – homocysteinuria – which leads to high levels of homocysteine in the blood or urine (body fluids as recited in Claim 13) of subjects suffering from this disease.[7] Therefore, it is not a fundamental truth that elevated levels of homocysteine in a body fluid always means a deficiency of a B vitamin. An elevated level of homocysteine can also be correlated to a genetic disease, not a B vitamin deficiency. In view of such analysis, one should recognize that the claimed process is not synonymous with the existence of any basic scientific relationship between the assay result and the condition of the subject.

However, even if one were to assume that the relationship between homocysteine levels and vitamin deficiency is a fundamental truth, i.e., elevated homocysteine always means

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7. Homocysteinuria is an inherited disorder of the metabolism of the amino acid methionine. (*See* the National Institutes of Health, July 26, 2004 *http://www.mlm.nih.gov/medlineplus/ency/article/001199.html*.) Homocysteinuria is a genetic disorder in which blood and urine levels of homocysteine, a metabolite of the amino acid methionine, are significantly higher than the normal concentration. The genetic defect lies in an enzyme, cystathionine b-synthetase, which generates a substance called cystathionine from homocysteine. National Organization for Rare Diseases *http://www.rarediseases.org*).

a B vitamin deficiency, Claim 13 is not excluded from patentability based on the claimed subject matter. Just because a process claim includes a scientific principle, it does not necessarily follow that the process claim is outside the scope of statutory subject matter under 35 U.S.C. § 101. If the claim produces a practical result, it can still fall within the scope of patentable subject matter notwithstanding the recitation of a scientific principle.

In *Diehr*, the Court held that a claim for a process for curing rubber that included a mathematical algorithm encompassed statutory subject matter because use of the algorithm produced a practical result. *Diehr*, 450 U.S. at 186-187. Following the decision in *Diehr* and a long line of supporting Court decisions, the United States Patent and Trademark Office recently issued interim guidelines for examination of patent applications for subject matter eligibility. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility October 26, 2005, published in the Official Gazette November 22, 2005, *http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm*, hereinafter "Guidelines".

The Guidelines set forth two alternative criteria for determining whether a claim that contains a law of nature/scientific principle satisfies the requirements for patent eligible subject matter. Does the claimed invention "transform" an article or physical object to a different state or thing, or does the claimed invention otherwise produce a useful, concrete, and tangible result? Guidelines at 19; *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.2d 1368 (Fed. Cir. 1998).

> In determining whether a claim is for a 'practical application', the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is 'useful, tangible and concrete'."

Guidelines at 20; *AT&T Corp.*, 172 F.3d 1352 (Fed. Cir. 1999); *State Street Bank*, 149 F.2d 1368 (Fed. Cir. 1998); *In Re Alappat*, 33 F.3d 1526 (1994).

In *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 958 F.2d 1053, the court held that a method to analyze heartbeat falls within the confines of statutory subject matter. The process analyzed electrical signals from a patient's heart by converting the signal into a value and then comparing that value to a predetermined value to predict vulnerability to ventricular tachycardia immediately after heart attack. This process of analysis of heart activity transformed the heart's electrical activity into a useful result – the condition of the patient's heart. "[T]he '459 patent as a whole does not present a mathematical algorithm. The '459 patent is a method for detecting the risk of a heart attack, not the presentation and proposed solution of a mathematical problem." *Arrhythmia*, 958 F.2d. at 1066, Rader, J. concurring opinion, citing *Diehr*, 450 U.S. at 186.

> *Diehr* refocused the patentability inquiry on the terms of the Patent Act rather than on non-statutory, vague classifications. Under the terms of the Act, a 'process' deserves patent protection if it satisfies the Act's requirements.

Id. at 1066.

So too in the disputed Claim 13, the process assays/analyzes the homocysteine molecules in a body fluid and transforms that signal/data to detect a B vitamin deficiency. Accordingly, when read as a whole, Claim 13 is a process that satisfies the requirements of 101 and deserves patent protection.

Whereas the *Arrythmia* case involved the use of a machine, the Court of Appeals for the Federal Circuit has ruled that it is of little relevance whether a claim is directed to a machine or process for a 101 analysis. Claims do not fall outside of the realm of non-statutory subject matter merely because some or all of the steps are carried out by a human mind or involve thought processes. *In re Musgrave*, 431 F.2d 882, 892 (CCPA 1970). "If all the steps of a claimed process can be carried out in the human mind, examiners must determine whether the claimed process produces a useful, tangible and concrete result, i.e., apply the practical application test set forth in *State Street*." Guidelines at 47. The process steps of Claim 13 produce a concrete tangible and useful result of the homocysteine assay – the detection of a vitamin deficiency. Thus, Claim 13, when read as a whole, encompasses statutory subject matter.

II. Confirming the Patentability of Claim 13 Would Not Preempt the Use of a Scientific Principle by Others

One must ensure, however, that when a law of nature, mathematical algorithm or abstract idea is part of a seemingly patentable process that, in reality, the law of nature, algorithm or idea does not preempt the use of that law, algorithm or idea to foreclose other uses. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Funk Brothers Seed Co.*, 333 U.S. 127, 132 (1948);

see also Diehr, 450 U.S. at 191. Knowledge once in the public domain must remain in the public domain. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1970).

A. Claim 13 Does Not Remove the Existence of Knowledge from the Public Domain

As stated in *Diehr*,

> In contrast, the respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.

Diehr, 450 U.S. at 187.

The analogy to *Diehr* is convincing. The inventors of Claim 13 do not seek to patent a scientific principle. They seek to patent a process for detecting a B vitamin deficiency. Claim 13, when read as a whole, covers a method of detecting a cobalamin or folate deficiency by assaying and analyzing homocysteine in a body fluid. As discussed above, elevated homocysteine levels can indicate a vitamin deficiency or a genetic defect. Correlating the homocysteine assay results to a vitamin deficiency, as opposed to a genetic defect, is a practical application of assaying homocysteine levels.

Would confirming the patentability of Claim 13 remove the existence of the knowledge from the public domain? No. In their patent application, patentees disclosed to the world the invention that assaying homocysteine is predictive

of a vitamin B12 or folate deficiency in a human. Patentees have not removed information from the public domain, but added to the public knowledge by disclosing a practical assay for the detection of cobalamin and folate deficiencies in humans. Prior to patentees' disclosure such a method was not known.

Moreover, information on cobalamin and folate deficiencies is still readily available. Scientific journals are not prohibited from publishing studies on vitamin deficiencies. Dissemination of critical medical information is still possible. Doctors and medical researchers are free to discuss and elaborate on the implications of homocysteine levels and vitamin deficiencies, or heart disease or genetic disease. No restriction on the dissemination of such medical information is precluded by confirming the patentability of Claim 13.

B. The Effects of Patenting a Medical Process Are No Different From Patenting a Medical Device

The quid pro quo for disclosing their invention to the world is that patentees now hold the legal right to exclude others from practicing their invention. Although legally permissible, in practice, common sense dictates that patentees cannot enforce their rights against every infringer. However, Diehr *can* exclude others from curing rubber using the patented process. State Street Bank *can* exclude others from practicing their patented method of investment configuration. Arrhythmia Research Technology *can* exclude others from using their patented electrocardiograph device from detecting heart irregularities. By confirming the patentability of Claim 13 the Court confirms the legal right of Respondents to exclude others from practicing their patented process of detecting a B vitamin deficiency.

Perhaps it is easier to appreciate exclusivity conferred on a machine or a device because it is a tangible object. Recently issued medical device patents include patents for artificial heart valves (*e.g.*, U.S Patent 6,991,649); coated medical devices (*e.g.*, U.S. Patent 6,921,811); artificial limbs (*e.g.*, U. S. Patent 6,936,073); and orthopedic splints (*e.g.*, U.S. Patent 6, 991,612). These medical devices are also premised on scientific principles. The functionality of an artificial heart valve is based on the scientific principles of fluid dynamics. Artificial limbs are based on the scientific principles of mechanical dynamics. Yet a patentee who patents a life-saving artificial heart valve or an artificial limb is granted a limited monopoly on their invention without question of pre-emption of a scientific principle. No distinction should be imposed because the subject matter is a medical process. The patent laws clearly include processes within the realm of patentable subject matter. Exclusivity conferred on a patented medical process should be treated no differently from the exclusivity conferred on patented medical devices.

C. The Intent of the Constitution and Congress is Safeguarded

The intent of the Constitution is to promote the progress of science and the useful arts. This directive has been supported by Congress and upheld by case law. Claim 13 confers on patentees a limited monopoly for a method of detecting a vitamin deficiency in a human by assaying homocysteine levels. Disclosure of this method has clearly advanced the knowledge of medical technology, for a reliable test for detecting B vitamin deficiencies in a human by analyzing levels of homocysteine was not previously known.

But, just because the patentees discovered a method of detecting a vitamin deficiency that is the current "state-of-the-art," it does not mean that others cannot improve on the method. In the future, someone may discover another method of detecting vitamin deficiencies that supplants the method of Claim 13, and that latter methods will become "state-of-the-art." Scientific research is not stagnant, and innovative advances are built on the knowledge of others. If there is a medical problem to be solved, someone will invent a solution. The competitive spirit will persist despite a patent being granted on a medical process or device. As we all know, designing around a patent is a well-recognized, and legal, exercise of technological innovation. The claimed process may confer exclusive rights on the patentees, but other researchers will continue in their quest to improve the technology.

But how will these "design-around" innovations be invented? Who will pay for the research? Are there only altruistic motives driving medical discovery? A significant driving force behind innovation and invention is financial reward. Medical researchers compete for limited amounts of research dollars to continue their research, relying heavily on their previous successes. Government grant applications request lists of patents as well as scientific publications. Medical institutions use patent license revenues to supplement government grant money designated for research. Technology-based companies, whether large or small, also rely on patented inventions to attract investor funding for growth. The rewards that stem from patented technology are critical components of the forces that drive innovation. Our forefathers recognized this when they conveyed the right of a limited monopoly to an inventor so that inventors could reap the rewards of their innovative achievements. Thus, confirming the patentability of Claim 13 will not hinder innovation, and the public will continue to be served by scientific and technological progress.

CONCLUSION

Respondent's method of correlating an elevated level of total homocysteine in the body fluid of a warm-blooded animal with a deficiency of cobalamin or folate is patent eligible subject matter. Correlating test results, as prescribed by Claim 13, does not impose a monopoly over a basic scientific relationship used in medical treatment. Any doctor looking at a test result of an assay suitable for complying with the assaying step of Claim 13 does not infringe the patent merely by thinking about a relationship between an elevated level of total homocysteine and a deficiency of cobalamin or folate. The monopoly conferred by a valid method patent, which is based on discovery of a basic scientific relationship, extends only to those who conduct a test for the purpose of correlating the test result with a condition associated with the relationship.

Where the test is known in the art, the application of the test is a limitation on the use of the test, just as discovery of a new use for a known device, likely also based on a "basic scientific relationship," is a limitation on the use of the device. In both cases, the monopoly does not exclude others from using the basic scientific relationship, only the claimed method.

We believe that Claim 13, when read as a whole, encompasses statutory subject matter under 35 U.S.C. § 101 as envisioned by the Constitution and Congress, and as supported by the Courts. We further believe that confirming the patentability of Claim 13 would not preempt the use of a scientific principle or remove the existence of knowledge from the public domain.

Respectfully submitted,

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